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determine an inflection point on the graph of neurotransmitter level, and wherein the inflection point is used to determine the therapeutic range.

Remarks

By this Amendment, claims 1-2, and 4-10, 12-15, 19-20, 24-27, 33-35, 37-45 and 51-53 are pending. Claim 3 is cancelled. Claims 1, 4-7, 10, 33, 37-41, 44, 51 and 53 are amended. The reasons for the claim amendments are discussed in detail below. No new matter has been added and support for these amendments can be found throughout the specification of the original application as filed.

Claim Rejects Under 35 U.S.C. §112

For clarity, Applicant's remarks address the rejections made in the office action in the order in which the rejections were made. The office action states that claim 1 is rejected under 35 U.S.C. §112 because it is unclear what the phrase, "determining a patient's health status with respect to neurotransmitter dysfunction" means. Claim 1 has been amended to clarify this term.

The office action states that claim 4 was rejected under 35 U.S.C. §112 because the term "health status" is unclear. As in claim 1, claim 4 has been amended to clarify this term. The office action states that claims 5-7 were rejected under 35 U.S.C. §112 because the term, "wherein the step of assaying is implemented via the subject's" serum, saliva and urine fluid is unclear. Claims 5-7 have been amended to clarify this term.

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The office action states that claim 12 was rejected under 35 U.S.C. §112 because the term, "wherein the neurotransmitter is serotonin and catecholamine" is unclear. Claim 12 has been amended to clarify this term.

The office action similarly rejected claim 44 stating that the term, "a combination of serotonin and catecholamine" is unclear. As in claim 12, claim 44 has been amended to clarify this term.

With respect to the ranges defined in the application, Applicant notes that the ranges are representative example ranges of a particular laboratory and one of ordinary skill in the art will recognize that actual ranges will vary based on individual laboratory equipment calibrations. The office action states that claim 13 was rejected because the term, "baseline reference point" is vague and indefinite. The term "baseline reference point" is defined in paragraphs 0066-0072 of the application.

The office action states that claim 14 was rejected because the term, "reference range" is vague and indefinite. The term "reference range" is defined by example representative ranges in paragraphs 0048-0052 of the application.

The office action states that claim 19 was rejected because the terms, "baseline reference point" and "optimal range" are vague and indefinite. The term "baseline reference point" is defined in paragraphs 0066-0072 and the term "optimal range" is defined by example representative ranges in paragraphs 0053-0057 of the application.

The office action states that claim 24 was rejected because the term, "reference range" is vague and indefinite. As stated above, the term "reference range" is defined by example representative ranges in paragraphs 0048-0052 of the application.

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The office action rejected claims 25-26 stating that the terms "therapeutic range" and "therapeutic point" are unclear. The term "therapeutic range" is defined by example representative ranges in paragraphs 0058-0064 and the term "therapeutic point" is defined in the original claims themselves as a neurotransmitter status point within the therapeutic range.

The office action rejected claim 33 stating that the term "graphing neurotransmitter level over time" is unclear. Claim 33 has been amended to clarify this term.

The office action rejected claim 34 stating that the term "inflection point" is unclear. The term "inflection point" is defined in paragraphs 0025-0028 of the application.

The office action rejected claim 35 stating that the term "the inflection point is used to determine the therapeutic range" is unclear. As stated hereinabove, the term "inflection point" is defined in paragraphs 0025-0028 and the term "therapeutic range" is defined by example representative ranges in paragraphs 0058-0064 of the application.

The office action states that claim 37 was rejected because the term "therapeutic range" is vague and indefinite. As stated above, the term "therapeutic range" is defined by example representative ranges in paragraphs 0058-0064 of the application.

The office action rejected claim 38 stating that the term "health status" is unclear. Claim 38 has been amended to clarify this term.

The office action states that claims 39-42 are indefinite for all the reasons that the claims from which they depend are indefinite and further because the term "wherein the step of assaying is implemented via the subject's" is unclear. Claims 39-41 have been amended to clarify the term. The rejections to the base claims have been addressed hereinabove

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The office action states that claim 51 was rejected because the term "graphing neurotransmitter over time" is indefinite. As in claim 33, claim 51 has been amended to clarify this term. Claim 51 was further rejected because the office action stated that the terms "determining an inflection point" and "wherein the inflection point is used to determine the therapeutic range" are indefinite. The term "inflection point" is defined in paragraphs 0025-0028 and the term "therapeutic range" is defined by example representative ranges in paragraphs 0058-0064 of the application. Further discussion of the inflection point and therapeutic range is found at paragraphs 0082-0083 of the application.

The office action rejected claim 52 for the same reasons it rejected claim 51 and the office action further stated that the term "therapeutic range" is unclear. As stated hereinabove, the term "therapeutic range" is defined by example representative ranges in paragraphs 0058-0064 of the application. The rejection of claim 51 was addressed above.

The office action rejected claim 53 under 35 U.S.C. §112. Claim 53 has been amended to clarify the terms subject to the rejection.

Claim 33 was further rejected because the term "administration step" lacks an antecedent basis. Claim 33 has been amended to cure this defect.

Claim Rejections Under 35 U.S.C. 102(b)

The office action rejected claims 1-3, 7-10, 13-14, 19 and 24-26 as being anticipated by Curtius et al., U.S. Patent No. 4,774,244. This rejection is respectfully traversed. Curtius et al. does not teach administering amino acid precursors of neurotransmitters as recited in currently amended claim 1. In contrast, Curtius et al. only discloses the administration of pharmaceutical cofactors. Therefore, Applicants respectfully request the withdrawal of the rejection of claim 1

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under 35 U.S.C. § 102. Claims 2, 7-10, 13-14, 19 and 24-26 are dependent claims and based on the foregoing amendment to the claim 1 from which they depend, Applicants respectfully request the withdrawal of the rejection of claims 2, 7-10, 13-14, 19 and 24-26 under 35 U.S.C. § 102.

The office action also rejected claims 1-2, 4-5, 7, 10, 13-14, 19, 24-26, 37-39 and 41 as being anticipated by the article authored by Ross entitled, "The Diet Cure." This rejection is respectfully traversed. Ross does not teach assaying the neurotransmitter level to determine a neurotransmitter status point nor does Ross teach administering an amino acid precursor for neurotransmitters as recited in independent claims 1 and 37. In contrast, Ross only discloses measuring the level of amino acids. One of ordinary skill in the art would recognize that testing for amino acid levels is quite different than measuring neurotransmitter levels. Therefore, Applicants respectfully request the withdrawal of the rejection of claims 1 and 37 under 35 U.S.C. § 102. Claims 2, 4-5, 7, 10, 13-14, 19, 24-26, 38-39 and 41 are dependent claims and based on the foregoing amendment to the base claims from which they depend, Applicants respectfully request the withdrawal of the rejection of claims 4-5, 7, 10, 13-14, 19, 24-26, 38-39 and 41 under 35 U.S.C. § 102.

Claim Rejections Under 35 U.S.C. 103(a)

The office action rejected claims 1-2, 4-5, 7, 10, 13-14, 19, 24-26, 33, 37-39 and 41 as being obvious in light of Ross. A *prima facie* case of obviousness of Applicants' claimed invention has not been established, as the cited references do not teach, suggest, or motivate all of the features included in independent claims 1 and 37. *Prima facie* obviousness is not established if all the

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elements of the rejected claim are not disclosed or suggested in the cited art. In re Ochiai, 37 USPQ 1127, 1131 (Fed. Cir. 1995). ("The test for obviousness *vel non* is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.'"). See also, MPEP § 2143.03 "All Claim Limitations Must Be Taught or Suggested," citing In re Royka, 180 USPQ 580 (CCPA 1974). "To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03. As stated above, Ross only generally discloses testing for amino acids levels. There is absolutely no disclosure in Ross of testing for neurotransmitter levels or administering amino acid precursors for neurotransmitters as recited in independent claim 1 and 37.

The office action also rejected claims 1-2, 4-5, 7, 10, 13-14, 19, 24-26, 33, 37-39, 41-44 as being obvious in light of Ross in further view of Curtius et al. Again, there is no teaching in either reference of at least the administration of amino acid precursors for neurotransmitters as recited in independent claims 1 and 37.

Thus, a *prima facie* of obviousness has not been established. With respect to specific features noted by the office action in the claims depending from claims 1 and 37, these issues are not commented on further here because they are presently moot given the above analysis, although Applicants do not acquiesce in the Examiner's position. See MPEP § 2143.03 ("If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.") As such, Applicants respectfully request allowance of claims 1-2, 4-5, 7, 10, 13-14, 19, 24-26, 33, 37-39 and 41.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

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The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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